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September 20, 2002

Commissioner for Patents  
Washington, D.C. 20231

Re: U.S. Patent Application No.: 09/939011  
For: DEVICE FOR IDENTIFYING THE PRESENCE OF A NUCLEOTIDE  
SEQUENCE IN A DNA SAMPLE  
Inventors: BENN, James *et al.*  
Filed: August 24, 2001  
Our Ref. No.: GEN-007ACP

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Dear Sir:

I enclose herewith for filing in the above-identified application the following:

1. Information Disclosure Statement;
2. PTO Form 1449;
3. Copies of references cited in PTO Form 1449 (147);
4. A copy of the International Search Report issued in international application no. PCT/US01/2655, filed August 24, 2001; and
5. A Return Postcard.

No additional costs are believed to be due in connection with the filing of this Information Disclosure Statement. However, please charge any necessary fees in connection with the enclosed statement to our Deposit Order Account No. 12-0080. For this purpose, a duplicate of this sheet is attached.

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September 20, 2002  
Date  
Peter C. Lauro  
Peter C. Lauro, Esq., Reg. No. 32,360

Respectfully submitted,  
LAHIVE & COCKFIELD, LLP

Peter C. Lauro, Esq.  
Registration No. 32,360  
Attorney for Applicants



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

#15

In re the application of: BENN, James *et al.*

Group Art Unit: 1645

Serial No.: 09/939011

Examiner:

Filed: August 24, 2001

For: DEVICE FOR IDENTIFYING THE PRE-  
SENCE OF A NUCLEOTIDE SEQUENCE IN A  
DNA SAMPLE

Attorney Docket No.: GEN-007ACP

Commissioner for Patents  
Washington, D.C. 20231

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Date of Signature and of Mail Deposit

By:

Peter C. Lauro  
Peter C. Lauro, Esq.  
Registration No. 32,360  
Attorney for Applicants

**INFORMATION DISCLOSURE STATEMENT**

Dear Sir:

Applicants and their Attorney are aware of the following publications and information, listed on the attached PTO Form 1449, and in accordance with 37 CFR §1.97 hereby submit these publications for the Examiner's consideration. A copy of each cited publication is enclosed. Please note that in the PTO Form 1449, document nos. A8, A24, B1, B3 and B8 were cited in the International Search Report issued for international application no.

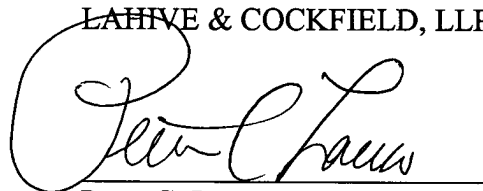
PCT/US01/2655, filed August 24, 2001, that corresponds to the above-referenced patent application. A copy of the International Search Report is also enclosed.

This statement is not to be interpreted as a representation that the cited publications are material, that an exhaustive search has been conducted, or that no other relevant information exists. Nor shall the citation of any publication herein be construed *per se* as a representation that such publication is prior art. Moreover, Applicants understand that the Examiner will make an independent evaluation of the cited publications.

Under 37 CFR § 1.97(b)(3), no additional costs are believed to be due in connection with the filing of this disclosure. If, however, a first Office Action on the merits issues in this application bearing a mailing date prior to the date of this Information Disclosure Statement, please charge the appropriate fee as required under 37 CFR §1.17(p) to our Deposit Order Account No. 12-0080.

Respectfully submitted,

LAHIVE & COCKFIELD, LLP

A handwritten signature in cursive script, appearing to read "Peter C. Lauro", written over a horizontal line.

Peter C. Lauro, Esq.  
Registration No. 32,360  
Attorney for Applicants

28 State Street  
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Date: September 20, 2002

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LIST OF PUBLICATIONS CITED BY APPLICANT  
(Use several sheets if necessary)

APPLICANT

BENN, James *et al.*

FILING DATE

August 24, 2001

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## U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	A1	3,915,652	10/75	Natelson	23	259	
	A2	4,458,066	07/84	Caruthers <i>et al.</i>	536	27	
	A3	4,500,707	02/85	Caruthers <i>et al.</i>	536	27	
	A4	4,650,750	03/87	Giese	435	7	
	A5	4,683,195	07/87	Mullis <i>et al.</i>	435	6	
	A6	4,769,216	09/88	Chandler <i>et al.</i>	422	58	
	A7	5,030,555	07/91	Clemmons	435	5	
	A8	5,188,963	02/93	Stapleton	435	299	
	A9	5,230,866	07/93	Shartle <i>et al.</i>	422	103	
	A10	5,352,609	10/94	Boquet	435	270	
	A11	5,391,480	02/95	Davis <i>et al.</i>	435	6	
	A12	5,449,064	09/95	Hogan <i>et al.</i>	204	180.1	
	A13	5,516,931	05/96	Giese <i>et al.</i>	560	59	
	A14	5,602,273	02/97	Giese <i>et al.</i>	560	60	
	A15	5,604,104	02/97	Giese <i>et al.</i>	435	7.1	
	A16	5,610,020	03/97	Giese <i>et al.</i>	435	7.1	
	A17	5,679,310	10/97	Manns	422	102	
	A18	5,785,926	07/98	Seubert <i>et al.</i>	422	100	
	A19	5,840,573	11/98	Fields	435	287.2	
	A20	5,856,174	01/99	Lipshutz <i>et al.</i>	435	286.5	
	A21	5,888,819	03/99	Goelet <i>et al.</i>	435	5	
	A22	5,985,651	11/99	Hunicke-Smith	435	285.1	
	A23	6,004,744	12/99	Goelet <i>et al.</i>	435	5	

## FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
							YES	NO
	A24	DE 199 50 385 A1	08/00	Germany			Abstract Only	
	A25	EP 616218 A1	09/94	EPO				
	A26	EP 697242 A1	02/96	EPO				
	A27	EP 805350 A1	11/97	EPO				
	A28	EP 903176 A2, A3	03/99	EPO				
	A29	JP 07-203965 A	08/95	Japan			Abstract Only	
	A30	JP 62-155090 A	07/87	Japan			Abstract Only	
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		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
							YES	NO
	B1	WO 88/04428 A1	06/88	WO				
	B2	WO 93/01312 A1	01/93	WO				
	B3	WO 96/07917 A1	03/96	WO			Abstract Only	
	B4	WO 97/29212 A1	08/97	WO				
	B5	WO 97/48818 A1	12/97	WO				
	B6	WO 98/04920 A2, A3	02/98	WO				
	B7	WO 99/13312 A1	03/99	WO				
	B8	WO 00/44497 A1	03/00	WO				
	B9	WO 00/66607 A1	11/00	WO				

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	B10	Bartsch, H. <i>et al.</i> (1996). "The role of individual susceptibility in cancer burden related to environmental exposure." <i>Environ. Health Perspect.</i> 104 Suppl. 3: 569-77
	B11	Bashkin, J. <i>et al.</i> (1996). "Implementation of a capillary array electrophoresis instrument." <i>J. Capillary Electrophor.</i> 3: 61-68
	B12	Beaucage, S.L. <i>et al.</i> (1981). "Deoxynucleoside phosphoramidites – a new class of key intermediates for deoxypolynucleotide synthesis." <i>Tetrahedron Letters</i> , 22(20): 1859-62
	B13	Beck, W. T. <i>et al.</i> (1993). "Altered DNA topoisomerase II in multidrug resistance." <i>Cytotechnology</i> 11(2): 115-9
	B14	Belgrader, P. <i>et al.</i> (1996). "Automated polymerase chain reaction product sample preparation for capillary electrophoresis analysis." <i>J. Chromatogr. B. Biomed. Appl.</i> 683(1): 109-14
	B15	Bioanalytical Systems, Inc. "BAS Rapid desalting dialyzer," retrieved from <a href="http://www.bioanalytical.com/products/md/desalter.html">http://www.bioanalytical.com/products/md/desalter.html</a> .
	B16	Boddy, A. V. <i>et al.</i> (1993). "The role of pharmacogenetics in chemotherapy: modulation of tumour response and host toxicity." <i>Cancer Surv.</i> 17: 79-104
	B17	Boffa, L.C. <i>et al.</i> (1995). "Isolation of active genes containing CAG repeats by DNA strand invasion by a peptide nucleic acid." <i>Proc. Natl. Acad. Sci. USA</i> 92: 1901-05
	B18	Bradshaw, D. M. <i>et al.</i> (1998). "Clinical relevance of transmembrane drug efflux as a mechanism of multidrug resistance." <i>J. Clin. Oncol.</i> 16(11): 3674-90
	B19	Caporaso, N. E. <i>et al.</i> (1994). "Molecular epidemiology: a new perspective for the study of toxic exposures in man. A consideration of the influence of genetic susceptibility factors on risk in different lung cancer histologies." <i>Med. Lav.</i> 85(1): 68-77
	B20	Caporaso, N. E. <i>et al.</i> (1995). "Genetic susceptibility in the occupational setting: introduction to the workshop." <i>Med. Lav.</i> 86: 199-206
	B21	Cardullo, E. <i>et al.</i> (1988). "Detection of nucleic acid hybridization by nonradiative fluorescence resonance energy transfer." <i>Proc. Natl. Acad. Sci. USA</i> 85: 8790-8794
	B22	Carrilho, E. <i>et al.</i> , (1996). "Rapid DNA sequencing of more than 1000 bases per run by capillary electrophoresis using replaceable linear polyacrylamide solutions." <i>Anal. Chem.</i> 68: 3305-3313

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C1	Carrilho, E. et al. (1997). "Factors to be considered for robust high-throughput automated DNA sequencing using a multiple-capillary array instrument." In <i>Progress in Biomedical Optics</i> , Cohn, G.E. and Soper, S.A. eds., B. L. Proc. SPIE 2985A, 4-18		
C2	Cline, J. et al. (1996). "PCR fidelity of <i>Pfu</i> DNA polymerase and other thermostable DNA polymerases." <i>Nucleic Acids Res.</i> 24(18): 3546-51		
C3	Dovich, N. J. (1997). "DNA sequencing by capillary electrophoresis." <i>Electrophoresis.</i> 18: 2393-2399		
C4	Drake, J. W. (1969). "Genetic control of mutation rates in bacteriophage T4." <i>Nature.</i> 221(5186): 1128-32		
C5	Dubiley, S. et al. (1997). "Fractionation, phosphorylation and ligation on oligonucleotide microchips to enhance sequencing by hybridization." <i>Nucleic Acid Res.</i> 25(12): 2259-65		
C6	Egholm, M. et al. (1993). "PNA hybridizes to complementary oligonucleotides obeying the Watson-Crick hydrogen-bonding rules." <i>Nature.</i> 365: 566-68		
C7	Eichelbaum, M. et al. (1996). "Influence of pharmacogenetics on drug disposition and response." <i>Clin Exp Pharmacol Physiol.</i> 23(10-11): 983-5		
C8	Evensen, H. T. et al. (1998). "Automated fluid mixing in glass capillaries." <i>Rev. Sci. Instrum.</i> , 69(2): 519-526		
C9	Ewing, B. L. et al. (1998). "Base-calling automated sequencer traces using Phred. I. Accuracy assessment." <i>Genome Res.</i> 8(3): 175-85		
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C11	Fei, Z. et al. (1998). "MALDI-TOF mass spectrometric typing of single nucleotide polymorphisms with mass-tagged ddNTPs." <i>Nucleic Acids Res.</i> 26(11):2827-8		
C12	Fung, E. N. et al. (1995). "High-Speed DNA Sequencing by Using Mixed Poly(ethylene oxide) Solutions in Uncoated Capillary Columns." <i>Anal. Chem.</i> 67(13): 1913-19		
C13	Giese, R. (2000). "Electron-capture mass spectrometry: recent advances." <i>J. Chromatogr. A.</i> 892: 329-346.		
C14	Goldstein, J. A. et al. (1997). "Frequencies of the defective CYP2C19 alleles responsible for the mephenytoin poor metabolizer phenotype in various Oriental, Caucasian, Saudi Arabian and American black populations." <i>Pharmacogenetics</i> 7(1): 59-64		
C15	Gordon, D. et al. (1998). "Consed: a graphical tool for sequence finishing." <i>Genome Res.</i> 8(3): 195-202		
C16	Hacia, J. G. et al. (1996). "Detection of heterozygous mutations in BRCA1 using high density oligonucleotide arrays and two-colour fluorescence analysis." <i>Nat. Genet.</i> 14:441-447		
C17	Hacia, J. G. et al. (1998). "Applications of DNA chips for genomic analysis." <i>Mol. Psychiatry</i> 3(6): 483-92		
C18	Hacia, J. G. et al. (1998). "Evolutionary sequence comparisons using high-density oligonucleotide arrays." <i>Nat. Genet.</i> 18(2): 155-8		
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D1	Hacia, J. G. <i>et al.</i> (1999). "Determination of ancestral alleles for human single-nucleotide polymorphisms using high-density oligonucleotide arrays." <i>Nat. Genet.</i> 22(2):164-7		
D2	Haff L. <i>et al.</i> , "A high-performance system for automation of the polymerase chain reaction." <i>BioTechniques</i> . 10:102-103, 106-12, (1991)		
D3	Harris, J. R. <i>et al.</i> (1992). "Breast cancer (first of three parts)." <i>N. Engl. J. Med.</i> 327(5): 319-28		
D4	Hayashi, S. <i>et al.</i> (1992). "High susceptibility to lung cancer analyzed in terms of combined genotypes of P450IA1 and Mu-class glutathione S-transferase genes." <i>Jpn. J. Cancer Res.</i> 83(8): 866-70		
D5	Hunnicke-Smith, S.P. (1997). "PCR and cycle sequencing reactions: a new device and engineering model," Ph.D. Dissertation, Stanford Univ., Stanford, CA, USA.		
D6	Hwang, D. <i>et al.</i> (1998). "Expression of cyclooxygenase-1 and cyclooxygenase-2 in human breast cancer." <i>J. Natl. Cancer Inst.</i> 90(6): 455-60		
D7	Ju, J. <i>et al.</i> (1995). "Fluorescence energy transfer dye-labeled primers for DNA sequencing and analysis." <i>PNAS USA</i> . 92(10): 4347-51		
D8	Karger, A. E. (1996). "Separation of DNA sequencing fragments using an automated capillary electrophoresis instrument." <i>Electrophoresis</i> . 17(1): 144-51		
D9	Kaye, S. B. (1998). "Multidrug resistance: clinical relevance in solid tumours and strategies for circumvention." <i>Curr. Opin. Oncol.</i> 10 Suppl 1: S15-S19		
D10	Kelley, D. J. <i>et al.</i> (1997). "Benzo[a]pyrene up-regulates cyclooxygenase-2 gene expression in oral epithelial cells." <i>Carcinogenesis</i> . 18(4): 795-9		
D11	Korch, C. <i>et al.</i> (1999). "Improved DNA sequencing accuracy and detection of heterozygous alleles using manganese citrate and different fluorescent dye terminators." <i>Genome Res.</i> 9(6): 588-95		
D12	Kwok, P-Y. <i>et al.</i> (1992). "Automatable screening of yeast artificial-chromosome libraries based on the oligonucleotide-ligation assay." <i>Genomics</i> . 13(4): 935-41		
D13	Lamoree, M. H. <i>et al.</i> (1998). "Application of microdialysis for on-line coupling of capillary isoelectric focusing with electrospray mass spectrometry on a magnetic sector instrument." <i>J. Mass Spectrometry</i> . 33: 453-460 (1998)		
D14	Lamoree, M. H. <i>et al.</i> (1997). "Use of microdialysis for the on-line coupling of capillary isoelectric focusing with electrospray mass spectrometry." <i>J. Chromatography A</i> . 777:31-39		
D15	Lench, N. <i>et al.</i> (1988). "Simple non-invasive method to obtain DNA for gene analysis." <i>Lancet</i> . 1(8599):1356-8		
D16	Linder, M. W. <i>et al.</i> (1997). "Pharmacogenetics: a laboratory tool for optimizing therapeutic efficiency." <i>Clin. Chem.</i> 43(2): 254-66		
D17	Liu, C. <i>et al.</i> (1998). "On-line dual microdialysis with ESI-MS for direct analysis of complex biological samples and microorganism lysates." <i>Anal. Chem.</i> 70(9): 1797-801		
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E1	Liu, C. <i>et al.</i> (1997). "Improving the microdialysis procedure for electrospray ionization mass spectrometry of biological samples." <i>J. Mass Spectrometry</i> . 32:425-431
E2	Longley, M. <i>et al.</i> (1999). "Isolation and mapping of the first ruminant multidrug resistance genes." <i>Anim. Genet.</i> 30(3): 207-10
E3	Lutz, E. S. M. <i>et al.</i> (1999). "On-line microdialysis-electrospray mass spectrometry for automated desalting of small-volume peptide samples." <i>Chromatographia Supp. I.</i> 49:S28-S34
E4	Majors, R.E. (1995). "Sample preparation perspectives: The use of membranes in sample preparation," <i>LC-GC</i> 13(5): 364-369, 371-373
E5	Marez, D. <i>et al.</i> (1997). "Polymorphism of the cytochrome P450 CYP2D6 gene in a European population: characterization of 48 mutations and 53 alleles, their frequencies and evolution." <i>Pharmacogenetics</i> 7(3): 193-202
E6	Marsh, M. <i>et al.</i> (1997). "High-throughput DNA sequencing on a capillary array electrophoresis system." <i>J. Capillary Electrophor.</i> 4(2): 83-89
E7	Masood, E. (1999). "... as consortium plans free SNP map of human genome." <i>Nature</i> . 398(6728): 545-6
E8	Masson, E. <i>et al.</i> (1997). "Pharmacokinetic optimisation of cancer chemotherapy: effect on outcomes." <i>Clin. Pharmacokinet.</i> 32(4): 324-43
E9	Mattila, P. <i>et al.</i> (1991). "Fidelity of DNA synthesis by the <i>Thermococcus litoralis</i> DNA polymerase—an extremely heat stable enzyme with proofreading activity." <i>Nucleic Acids Res.</i> 19(18):4967-73.
E10	Maxam, A. M. <i>et al.</i> (1977). "A new method for sequencing DNA." <i>PNAS USA</i> . 74: 560-4
E11	McGlynn, K. A. <i>et al.</i> (1995). "Susceptibility to hepatocellular carcinoma is associated with genetic variation in the enzymatic detoxification of aflatoxin B <sub>1</sub> ." <i>PNAS USA</i> . 92(6): 2384-7
E12	Mickley, L. A. <i>et al.</i> (1998). "Genetic polymorphism in <i>MDR-1</i> : a tool for examining allelic expression in normal cells, unselected and drug-selected cell lines, and human tumors." <i>Blood</i> . 91(5): 1749-56
E13	Nakachi, K. <i>et al.</i> (1993). "Polymorphisms of the CYP1A1 and glutathione S-transferase genes associated with susceptibility to lung cancer in relation to cigarette dose in a Japanese population." <i>Cancer Res.</i> 53(13): 2994-99
E14	Nebert, D. W. <i>et al.</i> (1999). "Genetic epidemiology of environmental toxicity and cancer susceptibility: human allelic polymorphisms in drug-metabolizing enzyme genes, their functional importance, and nomenclature issues." <i>Drug Metab. Rev.</i> 31(2): 467-487
E15	Nickerson, D. A. <i>et al.</i> (1997). "PolyPhred: automating the detection and genotyping of single nucleotide substitutions using fluorescence-based resequencing." <i>Nucleic Acids Res.</i> 25(14): 2745-51
E16	Nielsen, P.E. <i>et al.</i> (1991). "Sequence-selective recognition of DNA by strand displacement with a thymine-substituted polyamide." <i>Science</i> 254: 1497-1500
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F2	Raunio, H. <i>et al.</i> (1995). "Diagnosis of polymorphisms in carcinogen-activating and inactivating enzymes and cancer susceptibility -- a review." <i>Gene</i> 159(1): 113-21
F3	Rebbeck, T. R. <i>et al.</i> (1998). "Modification of clinical presentation of prostate tumors by a novel genetic variant in CYP3A4." <i>J. Natl. Cancer Inst.</i> 90(16): 1225-9
F4	Rieder, M. J. <i>et al.</i> (1998). "Automating the identification of DNA variations using quality-based fluorescence re-sequencing: analysis of the human mitochondrial genome." <i>Nucleic Acids Res.</i> 26(4): 967-73
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F6	Rose, D. J. "Characterization of antisense binding properties of peptide nucleic acids by capillary gel electrophoresis." <i>Anal. Chem.</i> 65: 3545-49 (1993).
F7	Ruiz-Martinez, M. C. <i>et al.</i> (1998). "A sample purification method for rugged and high-performance DNA sequencing by capillary electrophoresis using replaceable polymer solutions: A. Development of the cleanup protocol." <i>Anal. Chem.</i> 70(8): 1516-27
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F11	Shields, P. G. (1993). "Inherited factors and environmental exposures in cancer risk." <i>J. Occup. Med.</i> 35(1): 34-41
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F13	Subbaramaiah, K., <i>et al.</i> (1996). "Transcription of cyclooxygenase-2 is enhanced in transformed mammary epithelial cells." <i>Cancer Res.</i> 56(19): 4424-9
F14	Swerdlow, H. <i>et al.</i> (1997). "Fully automated DNA reaction and analysis in a fluidic capillary instrument." <i>Anal. Chem.</i> 69(5): 848-55
F15	Szakacs, G. <i>et al.</i> (1998). "Diagnostics of multidrug resistance in cancer." <i>Pathol. Oncol. Res.</i> 4(4): 251-57
F16	Tan, H. <i>et al.</i> (1997). "Integrated on-line system for DNA sequencing by capillary electrophoresis: from template to called bases." <i>Analytical Chem.</i> 69: 664-674
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G1		Tan, S. <i>et al.</i> (1992). "Development of a sensitive reverse transcriptase PCR assay, RT-PCR, utilizing rapid cycle times," <i>PCR Methods Appl.</i> 2(2): 137-43
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G4		Wang, P. <i>et al.</i> (2000). "Laser-induced electron capture mass spectrometry." <i>Anal. Chem.</i> 72(4): 772-6
G5		Wang, Z. <i>et al.</i> (1998). "N-hydroxysuccinimide ester labeling 5'-aminoalkyl DNA oligomers: reaction conditions and purification." <i>J. Chromatogr. A.</i> 806: 93-95
G6		Watson, P. <i>et al.</i> (1998). "Colorectal carcinoma survival among hereditary nonpolyposis colorectal carcinoma family members." <i>Cancer.</i> 83(2): 259-66
G7		Weiler, J. <i>et al.</i> (1997). "Hybridisation based DNA screening on peptide nucleic acid (PNA) oligomer arrays." <i>Nucleic Acid Res.</i> 25: 2792-99
G8		Willman, C. L. (1998). "Molecular genetic features of myelodysplastic syndromes (MDS)." <i>Leukemia.</i> 12 Suppl. 1: S2-S6
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G14		Yeung, E. S. and Q. Li (1998). "DNA sequencing by multiplexed capillary electrophoresis." in <i>High Performance Capillary Electrophoresis. Chemical Analysis Series.</i> Khaledi, M.G. (ed.); John Wiley & Sons, Inc. New York, NY. Vol. 146, pp. 767-789
G15		Zhang, N. <i>et al.</i> (1999). "Automated and integrated system for high-throughput DNA genotyping directly from blood." <i>Anal. Chem.</i> 71(6): 1138-45
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## U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	H1	4,709,016	11/87	Giese	530	389	
	H2	4,832,851	05/89	Bowers <i>et al.</i>	210	650	
	H3	4,902,481	02/90	Clark <i>et al.</i>	422	101	
	H4	5,360,819	11/94	Giese	514	538	
	H5	5,560,811	10/96	Briggs <i>et al.</i>	204	451	
	H6	5,650,270	07/97	Giese <i>et al.</i>	435	6	
	H7	5,856,100	01/99	Hayashizaki	435	6	

## FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
							YES	NO
	H8	EP 0 431905 A1, B1	06/91	EPO				
	H9	WO 87/07645 A1	12/87	WO				
	H10	WO 92/13963 A1	08/92	WO				
	H11	WO 00/66723 A1	11/00	WO				
	H12	WO 01/19482 A2, A3	03/01	WO				

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